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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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EXAMINER

ART UNIT

PAPER NUMBER

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No  
09/368,670

Applicant(s)  
Llinas-Brunet

Examiner  
David Lukton

Group Art Unit  
1653



X Responsive to communication(s) filed on May 22, 2000

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claim

X Claim(s) 1-28, 30-35, 37-92, and 96-102 is/are pending in the application.

Of the above, claim(s) 67-72, 75, 78, 81, 83, 84, 89-92, and 97-99 is/are withdrawn from consideration.

Claim(s) \_\_\_\_\_ is/are allowed.

X Claim(s) 1-28, 30-35, 37-66, 73, 74, 76, 77, 79, 80, 82, 85-88, 96, and 100-102 is/are rejected.

Claim(s) \_\_\_\_\_ is/are objected to.

Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All ☐ Some\* ☐ None ☐ of the CERTIFIED copies of the priority documents have been received.

received in Application No. / Series Code / Series Number(s) \_\_\_\_\_

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received \_\_\_\_\_

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s) \_\_\_\_\_

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Pursuant to the directives of paper No. 5 (filed 5/8/00), claims 1, 30, 33, 37, 41, 65, 68 have been amended, claims 29, 36, 93-95 cancelled, and claims 100-102 added. Claims 1-28, 30-35, 37-92, 96-102 are pending. Claims 1-28, 30-35, 37-66, 73, 74, 76, 77, 79, 80, 82, 85-88, 96, 100-102 are examined in this Office action; claims 67-72, 75, 78, 81, 83, 84, 89-92 and 97-99 are withdrawn from consideration.

Applicants' arguments filed 5/8/00 have been considered and found persuasive. The previously imposed rejections are withdrawn.

✻

Revision of the abstract is required. First, the abstract must be grammatically complete. The first line of the abstract could recite, for example the following:

*Disclosed herein are hepatitis C viral protease inhibitors of formula (I)...*

In addition, the length of the abstract should be reduced so that it is no more than about 2/3 of a page; a thorough definition of all the substituent variables is not required.

✻

The following is a quotation of the first paragraph of 35 U.S.C. §112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-35, 37-66, 73, 74, 76, 77, 79, 80, 82, 85-88, 96 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in

such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 1 recites the term "pharmaceutically acceptable"; claim 96 recites the term "therapeutically acceptable" in addition to "pharmaceutically acceptable". (See also, other independent claims such as claim 45). This implies an assertion of therapeutic efficacy. Applicants have shown that several of the claimed compounds are effective to inhibit HCV protease *in vitro*, however, it remains to be determined whether in fact this inhibition will occur *in vivo*, and if it does, whether it will lead to a perceptible improvement in the condition of a patient afflicted with such an infection. Extrapolation from the test tube to the intact mammal is a precarious proposition; more often than not predictions of success are not vindicated. It is suggested that the terms "therapeutically acceptable" and "pharmaceutically acceptable" be deleted.

✱

Claims 1-35, 37-66, 73, 74, 76, 77, 79, 80, 82, 85-88, 96 are rejected under 35 U.S.C. §112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, third line from last, the following is recited:

"A is hydroxy or a pharmaceutically acceptable salt of ester thereof"

First, the term "pharmaceutically acceptable salt" appears again two lines later in the claim; its presence at this point appears to be redundant. Second, the phrase recites in essence an

ester of a hydroxy group. This is inaccurate and misleading. Strictly interpreted, the group thus described would be an anhydride, which is probably not intended. Either of the following could be used:

*A is hydroxy, or A, taken together with the carbonyl group to which it is bonded, represents an ester group*

*A, taken together with the carbonyl group to which it is bonded, represents a carboxyl group or an ester group.*

Each of the independent claims that are drawn to compounds (e.g., 1, 40, 45, 72) is indefinite as to functional limitation. A functional limitation is required. The following is suggested for the first line of claim 1:

*A hepatitis C viral protease inhibitor compound of formula I, or a racemate, diastereomer or optical isomer thereof...*

Also, with respect to claim 1 (and other independent claims), if applicants intend to claim mixtures of compounds, as well as single, individual compounds, then a claim should be added which specifically recites a mixture, such as the following

*A mixture consisting of a compound according to claim 1, and at least one racemate, diastereomer or optical isomer thereof*

In claim 1, on the last line of page 3 of paper No. 5, within the definition of R<sub>2a</sub>, the following appears: "NR<sub>12</sub>R<sub>12a</sub>:". Applicants are requested to explain the purpose of the colon, or change it to a semicolon.

Applicants have directed that claim 23 be amended to delete "R<sub>13</sub>, wherein". However, if this is done, the definition of variable R<sub>2a</sub> then reads as follows:

R<sub>2a</sub> being substituted at any position with X is CH or N

This does not make sense grammatically. Clarification is sought.

Claim 32 recites "all of which optionally substituted". There is a grammatical error here. The following is suggested:

*each of which is optionally substituted.*

See also claim 63 with respect to this matter.

Claim 58 refers to "the P1 segment". The presence of "P1", "P2", "P3", "P4" above the formula (in claim 45) is noted; however, the term "P1 segment" could still be viewed as lacking antecedent basis. There must be some mention of the term "P1 segment" in claim 45, and some indication of what it means.

In claim 54, line 2, "naphtylmethoxy" is misspelled.

Claim 59 is drawn to a mixture of compounds, whereas claim 45, on which it depends is drawn to a single compound. A single compound is not a mixture.

One option would be to add a claim such as the following, and then to make claim 59 dependent on it:

*A mixture consisting of a compound according to claim 45, together with at least one stereoisomer thereof.*

Also in claim 59, the term "racemic mixture of diastereomers" is somewhat superfluous under the circumstances. Reference to just diastereomers would appear sufficient.


With respect to claims 48, 49, 55, 59, 60, 62, 66, applicants are requested to explain the purpose of the arrows, and to explain what would be lost if they were deleted.

In claim 61, the term "said asymmetric carbon" lacks antecedent basis in claim 58.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton. Phone: (703) 308-3213.

An inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

  
**DAVID LUKTON**  
**PATENT EXAMINER**  
GROUP 1653